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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,567

04/16/2004

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DXU-0007

2115

23377 7590 01/15/2009
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EXAMINER

TOTH, KAREN E

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

01/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/826,567	Applicant(s) LEC ET AL.	
	Examiner KAREN E. TOTH	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Applicant's arguments filed 24 October 2008 have been fully considered but they are not persuasive.

Regarding Applicant's argument that Grzegorzewski's piezoelectric element is not a signal driver, the Examiner still disagrees. Applicant has not provided any specialized definition of what constitutes a signal driver, nor is one described at any point in the specification. As such, the term is given its broadest reasonable interpretation, that being an element that produces a signal. A piezoelectric component, such as that of Grzegorewski, inherently produces a variable signal. The additional features Applicant has cited as belonging to a "signal driver" are not present in the disclosure, nor are they at any point tied to a "signal driver", since that component is not included in the disclosure of the invention.

Regarding Applicant's arguments that Freiherr Von Der Goltz does not disclose a signal processor that determines a blood characteristic in response to an applied signal, the Examiner disagrees. The cited control unit (element 18) works in cooperation with the pressure sensor (element 9) to determine the pressure in a chamber, where the pressure varies as a result of changes in blood characteristics. That is, as the pressure changes, it is directly connected to changes in the blood characteristics that are the

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result of an applied signal, with the measurement system being able to determine the changes in the blood characteristic based upon the aforementioned measurements.

Finally regarding the repeated arguments concerning the rejection under 35 USC 112 2nd, the Examiner maintains that it is not clear what is intended by the phrase "biological sensing media" because no description is provided in the disclosure. Though a direct quote is not required, there must be some way of relating what is claimed to the description of the invention in the disclosure. "Biological sensing media" is a very broad term, while the disclosure presents a more detailed description relating to what has been labeled as a "bio-sensing element". All of Applicant's remarks are drawn to various sensing elements, with no reference to media. The Examiner once again notes that merely amending the claims to match the language used in the disclosure would overcome this rejection.

Claim Rejections - 35 USC § 102

1. Claims 33, 36, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Freiherr Von Der Goltz (US Patent 7223365).

Regarding claim 33, Freiherr Von Der Goltz discloses a blood analysis device comprising a transducer element (column 3, lines 2-17; element 4), biological sensing media in communication with the transducer (column 2, lines 49-53), a signal driver in communication with the transducer for applying a signal to the transducer and varying it (element 17, 18), an inlet port for delivering blood to the transducer element (element

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5), and a signal processor in connection with the transducer for determining a blood characteristic from the blood's response to the varying signal (elements 9, 18).

Regarding claim 36, Freiherr Von Der Goltz further discloses a bioactive material on the transducer element (column 11, lines 50-62).

Regarding claim 42, Freiherr Von Der Goltz further discloses a catheter (element 57).

2. Claims 33-35, 37, 39, 43, 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Grzegorzewski (US Patent 5494639).

Regarding claim 33, Grzegorzewski discloses a blood analysis device comprising a transducer element (elements 14), biological sensing media in communication with the transducer (element 13), a signal driver in communication with the transducer for applying a signal to the transducer and varying it (element 8), an inlet port to direct blood to the transducer element (element 11), and a signal processor in communication with the transducer that determines a blood characteristic from the blood's response to the applied signal (element 52).

Regarding claim 34, Grzegorzewski discloses the transducer as an electrostrictive element (column 3, lines 39-61).

Regarding claim 35, Grzegorzewski further discloses the transducer including a plurality of sensors (electrodes 14).

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Regarding claim 37, Grzegorzewski discloses varying an applied frequency (column 3, lines 43-53; column 6, lines 8-10). Regarding claim 39, the Examiner notes that there are no alternatives to individual, sequential, and simultaneous delivery of a signal, and Grzegorewski's signal therefore inherently is delivered via one of these options.

Regarding claim 43, Grzegorewski's device can be used to test any subject's blood, including that of the person operating the unit.

Regarding claim 47, Grzegorzewski discloses a bulk bioactive material (element 13; column 3, lines 29-37).

Claim Rejections - 35 USC § 103

3. Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freiherr Von Der Goltz in view of Jina (US Patent 6673622).

Freiherr Von Der Goltz discloses all the elements of the claimed invention, as described above, except for the device comprising data storage, processing, and transmission of physiological characteristics and providing information to a patient. Jina teaches a blood characteristic analysis system comprising data storage, processing, and transmission, including storing blood data and providing information to a patient via a display (column 6 line 30 to column 7 line 23), in order to effectively analyze and use the gathered data. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Freiherr Von Der Goltz with

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data storage, processing, and transmission, and display of information, as taught by Jina, in order to effectively analyze and use the gathered data.

4. Claims 48 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freiherr Von Der Goltz in view of Stiene (US Patent Application Publication 2004/0072357).

Regarding claims 48 and 51, Freiherr Von Der Goltz discloses all the elements of the claimed invention, as described above, except for the device comprising data storage, processing, and transmission, and wired and wireless communication. Stiene teaches a blood characteristic analysis system comprising data processing, storage, and transmission, including wired and wireless communication between the device, a patient, and a health center (paragraphs [0044], [0055]-[0066], [0078], [0115]), in order to facilitate analysis of gathered data. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Freiherr Von Der Goltz with data processing, storage, and transmission, as well as wired and wireless communication, as taught by Stiene, in order to facilitate data analysis.

5. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freiherr Von Der Goltz.

The Examiner notes that Freiherr Von Der Goltz does not expressly disclose the effect generated by the transducer traveling between 1 nm and 1 cm into the blood from the transducer's surface. However, the distance the signal travels is a function of the

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sample volume, as well as the type of signal being applied and the strength and frequency of that signal. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to configure the device such that the transducer's effect would travel between 1 nm and 1 cm from its surface.

6. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grzegorzewski in view of Corey (US Patent Application Publication 2004/0054283).

Grzegorzewski discloses all the elements of the claimed invention, as described above, except for the frequencies including a resonant, antiresonant, harmonic, or anharmonic frequency. Corey teaches analyzing blood characteristics at a resonant frequency (paragraph [0113]), in order to accurately calculate hematocrit. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the system of Grzegorzewski at a resonant frequency, as taught by Corey, in order to obtain accurate measurements.

Allowable Subject Matter

7. Claims 38 and 44-46 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the invention of claim 38, including, *inter-alia*, a blood analysis device comprising a signal driver that applies a

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varying frequency signal to a transducer, where the range of the frequency is between 1 KHz and 10 GHz.

The prior art of record fails to anticipate or make obvious the invention of claim 44, including, *inter-alia*, a blood analysis device comprising two acoustic sensors, one for analyzing the blood and the other for comparing the blood to a reference fluid.

The prior art of record fails to anticipate or make obvious the inventions of claims 45 and 46, including, *inter-alia*, a blood analysis device coated with collagen or tissue thromboplastin.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735